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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SMITH & NEPHEW, INC.

Petitioner

v.

Patent Owner of

U.S. Patent No. 7,087,073 to Peter M. Bonutti

IPR Trial No. TBD

**PETITION FOR *INTER PARTES* REVIEW OF
U.S. PATENT NO. 7,087,073
UNDER 35 U.S.C. § 312 AND 37 C.F.R. § 42.104**

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I. MANDATORY NOTICES

A. Real Party-in-Interest

Smith & Nephew, Inc. (“Petitioner”) is the real party-in-interest and submits this *inter partes* review Petition (“Petition”) for review of a certain claim of U.S. Patent No. 7,087,073 (“the ’073 patent”).

B. Related Matters

The following litigation matter would affect or be affected by a decision in this proceeding: *Bonutti Skeletal Innovations LLC v. Smith & Nephew, Inc.*, Civil Action No. 12-1111-GMS (D. Del.). The litigation involves six patents: the ’073 patent and U.S. Patent No. 5,980,559, U.S. Patent No. 6,702,821, U.S. Patent No. 7,749,229, U.S. Patent No. 7,806,896, and U.S. Patent No. 8,133,229. The ’073 patent is the subject of this Petition. Separate petitions for *inter partes* review of the other patents above are being filed in addition to this Petition. Because the technology and disclosure in the patents are similar and for the sake of administrative efficiency and consistent outcome, Petitioner requests that the Patent Trial and Appeals Board (“PTAB”) have a single Administrative Panel address these *inter partes* reviews.

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II. CERTIFICATION OF GROUNDS FOR STANDING

Petitioner certifies pursuant to Rule 42.104(a) that the patent for which review is sought is available for *inter partes* review and that Petitioner is not barred or estopped from requesting an *inter partes* review challenging the patent claims on the grounds identified in this Petition.

III. OVERVIEW OF CHALLENGE AND RELIEF REQUESTED

Pursuant to Rules 42.22(a)(1) and 42.104(b)(1)-(2), Petitioner challenges claim 35 of the '073 patent (Ex. 1001).

A. Prior Art Patents and Printed Publications

Petitioner relies upon the following patents and printed publications:

1. U.S. Patent No. 4,955,910 (“Bolesky ’910” (Ex. 1003)), which has an issue date of Sep. 11, 1990, and is prior art to the ’073 patent under 35 U.S.C. § 102(b)¹.
2. U.S. Patent No. 5,500,000 (“Feagin ’000” (Ex. 1004)), which has an issue date of Mar. 19, 1996, and is prior art to the ’073 patent under 35 U.S.C. § 102(b).
3. U.S. Patent No. 5,569,306 (“Thal ’306” (Ex. 1005)), which has an issue date of Oct. 29, 1996, and is prior art to the ’073 patent under 35 U.S.C. § 102(b).
4. U.S. Patent No. 5,817,107 (“Schaller ’107” (Ex. 1009)), which has an issue date of Oct. 6, 1998, and is prior art to the ’073 patent under 35 U.S.C. § 102(b).

B. Grounds for Challenge

Petitioner requests cancellation of claim 35, the challenged claim, as unpatentable under 35 U.S.C. § 102(b) or, in the alternative, unpatentable under 35 U.S.C. § 103.

¹ The ’073 patent was issued prior to the America Invents Act (the “AIA”).

Therefore, Petitioner has chosen to use the pre-AIA statutory framework to refer to the prior art.

This Petition, supported by the declaration of Dr. Wayne Sebastianelli (“Sebastianelli Declaration” or “Sebastianelli Decl.” (Ex. 1002)) filed with this Petition, demonstrates that there is a reasonable likelihood that Petitioner will prevail with respect to at least one of the grounds for challenge and that each of the challenged claims is unpatentable for the reasons cited in this Petition. *See* 35 U.S.C. § 314(a).

IV. LEGAL PRINCIPLES

The challenged claim is unpatentable because it is anticipated under 35 U.S.C. § 102(b). A claim is anticipated if:

the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention

35 U.S.C. § 102(b). “A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of Calif.*, 814 F.2d 628, 631 (Fed. Cir. 1987).

Because the challenged claim here is directed to known methods disclosed in the prior art, the challenged claim is unpatentable, and an *inter partes* review of the challenged claim should be instituted.

The challenged claim is unpatentable because it is obvious under 35 U.S.C.

§ 103. A claim is invalid if it would have been obvious—that is:

[I]f the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which [the] subject matter pertains.

35 U.S.C. § 103; *see also Rockwell Int’l Corp. v. United States*, 147 F.3d 1358, 1364 (Fed. Cir. 1998).

In *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 415 (2007), the U.S. Supreme Court addressed the issue of obviousness and provided an “expansive and flexible approach” that is consistent with the “broad inquiry” set forth in *Graham v. John Deere Co.*, 383 U.S. 1 (1966). According to the Supreme Court, a person of ordinary skill in the art is “a person of ordinary creativity, not an automaton,” *KSR*, 550 U.S. at 421, and “in many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle.” *Id.* at 420.

The Court held that:

When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was

obvious to try might show that it was obvious under [35 U.S.C.]
§ 103.

Id. at 421. Thus, *KSR* focused on whether a combination of known elements could be patentable if it yielded predictable results. The Court’s guidance was clear: it may not. “The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.” *Id.* at 416. Further, “[i]f a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability.” *Id.* at 417.

The Board must ask, as guided by *KSR*, whether the challenged claim recites an improvement that is “more than the predictable use of prior art elements according to their established functions.” *Id.* at 417. The Board should conclude, based on the information in this Petition, that the challenged claim is merely a predictable combination of known elements that are used according to their established functions, that the claim is therefore unpatentable, and that an *inter partes* review of the challenged claim should therefore be instituted.

V. CLAIM CONSTRUCTION

A claim in *inter partes* review is given the “broadest reasonable construction in light of the specification.” 37 C.F.R. § 42.100(b).² Any claim term that lacks a definition in the specification is therefore also given a broad interpretation. *In re ICON Health & Fitness, Inc.*, 496 F.3d 1374, 1379 (Fed. Cir. 2007). Solely for the purposes of this proceeding, the following discussion proposes constructions of and support therefore of those terms in the claim listed below. Any claim terms not included in the following discussion are to be given their broadest reasonable interpretation in light of the specification as commonly understood by those of ordinary skill in the art. Moreover, should the Patent Owner, in order to avoid the prior art, contend that the claim has a construction different from its broadest reasonable interpretation, the appropriate course is for the Patent Owner to seek to amend the claim to expressly correspond to its contentions in this proceeding. *See* 77 Fed. Reg. 48764 (Aug. 14, 2012). Any such amendment would only be permissible if the proposed amended claim complies with 35 U.S.C. §112.

² The proposed claim constructions herein apply the “broadest reasonable construction” standard and a construction under a different standard of claim interpretation (*e.g.*, as applied in a District Court proceeding) may be different.

Claim 35 recites the term “predetermined tension.” This term is not defined in the specification. As discussed above it should be given its broadest reasonable interpretation. The commonly understood meaning of “predetermined” as defined in the dictionary is “to determine, decide, or decree beforehand.” Webster’s New World Dictionary (2d College ed. 1976). This definition is also consistent with how this term has been previously defined. *See, e.g., IGT v. Bally Gaming Int’l, Inc.*, 659 F.3d 1109, 1118 (Fed. Cir. 2011) (holding that “predetermined event” should be defined as “an event that is chosen in advance”). Therefore, Petitioner proposes that this term should mean “a tension that is determined beforehand or chosen in advance.”

Claim 35 also recites the term “interconnected.” This term is not defined in the specification. The commonly understood meaning of “interconnected” is “connected with one another.” Webster’s New World Dictionary (2d College ed. 1976). Therefore, Petitioner proposes that this term should mean “connected together.”

VI. OVERVIEW OF METHODS OF TISSUE FIXATION USING SUTURE ANCHORS

Tissue fixation using suture anchors is an orthopedic surgery technique that is predominantly used to fix soft tissues like tendons or muscle to bone.

Sebastianelli Decl. ¶ 16 (Ex. 1002). A suture anchor is a device, shaped, for

example, like a hook, nail, or screw, that is inserted into the body. *Id.* The anchor itself may fix a tissue to bone, or may be used to anchor a suture that is used to fix the tissue into place. *Id.* When a suture anchor is inserted into bone and holds a suture in place, it allows a surgeon to place large amounts of tension on a particular tissue by leveraging the suture against the anchor in the bone and then using the anchored suture to manipulate the tissue. *Id.*

The amount of tension required to complete a given tissue repair is dictated by a number of biological and anatomical factors. Sebastianelli Decl. ¶ 17 (Ex. 1002). For example, the extent of the injury can increase the amount of tension required to close the wound. *Id.* If the tear in the tissue is large, then the surgeon will necessarily need to apply more force to close the tear. *Id.* Additionally, the age of the injury is also critical to the amount of tension required for the repair. Immediately after an injury, the body's natural repair mechanisms are triggered. *Id.* Key among these is the formation of scar tissue. Because scar tissue is less pliable than normal tissue, more force is required to pull the tissue back to its anatomical location. *Id.* A surgeon will assess these and other factors during surgery in order to determine the amount of tension required to best to accomplish the repair. *Id.*

A surgeon can use multiple anchors to complete a repair. Sebastianelli Decl. ¶ 18 (Ex. 1002). When more than one anchor is used, generally the anchors are

placed on the opposite sides of the injury and then the sutures are used to pull the two tissues together to allow for healing to occur. *Id.* One particular common injury that involves the use of suture anchors in its repair is a torn rotator cuff in the shoulder. *Id.*

The shoulder is a complex joint that allows for the enormous range of motion of the human arm. Sebastianelli Decl. ¶ 19 (Ex. 1002). The mobility of the shoulder joint is provided by the muscles that make up the rotator cuff. *Id.* The diagram below shows the anatomy of the shoulder:

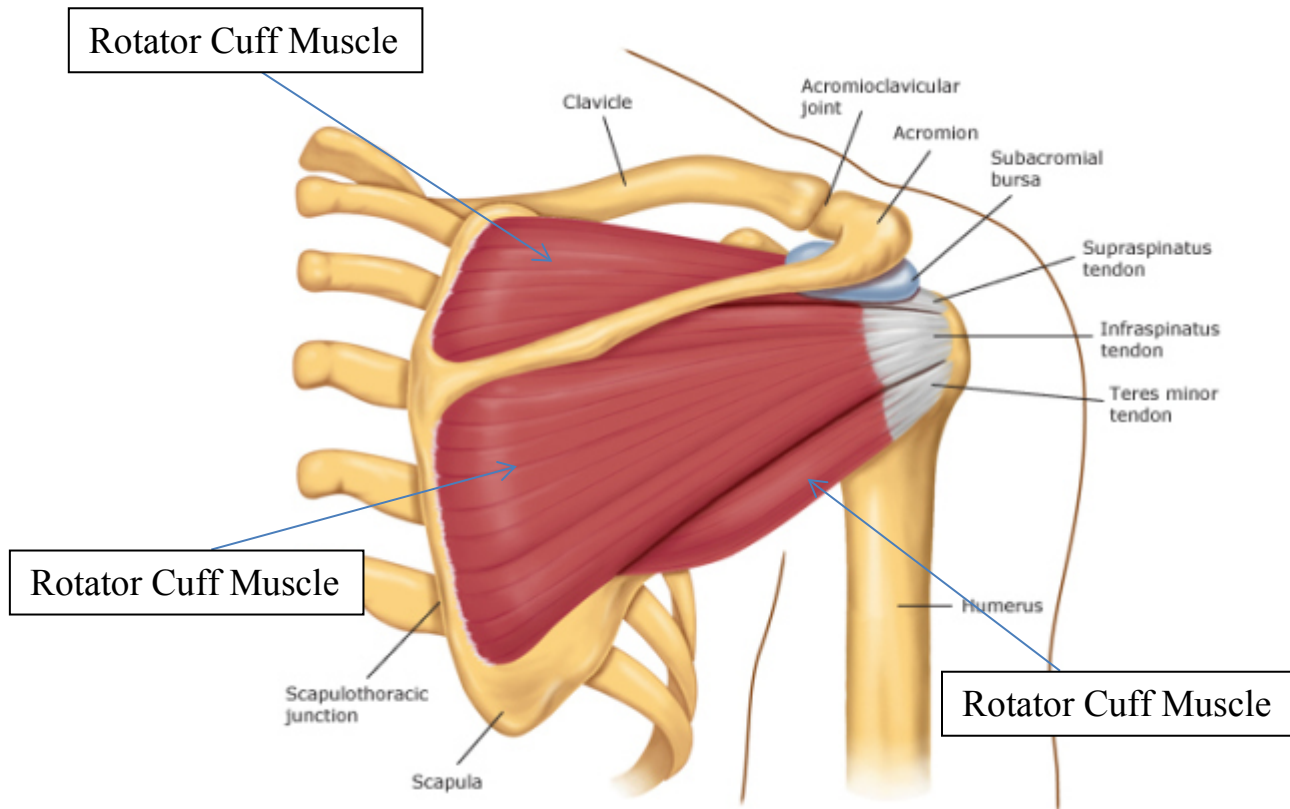


Diagram of Anatomy of Human Shoulder

The rotator cuff muscles extend from the scapula (shoulder blade) to the head of the humerus. Sebastianelli Decl. ¶ 20 (Ex. 1002). They connect the humerus to the shoulder and provide motor stability to the arm as it moves. *Id.* A rotator cuff tear involves a tear of the tendon and/or muscle of one of the rotator cuff muscles. *Id.* To repair a rotator cuff tear, a surgeon usually uses multiple suture anchors to reattach the tendon to the humeral head of the arm. *Id.* Below is a diagram of a typical repair:

FIG. 1: ROTATOR CUFF TEAR

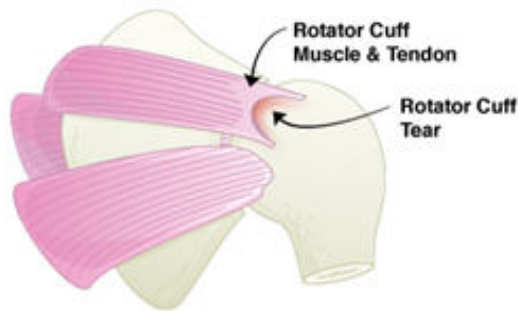


FIG. 2: MEDIAL ANCHORS

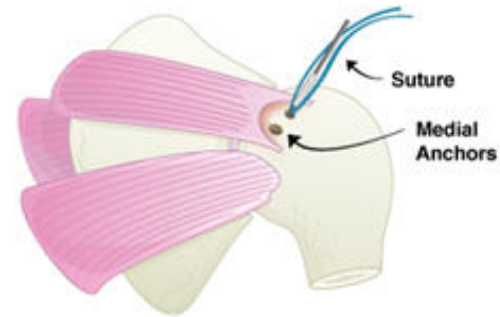


FIG. 3: MEDIAL ROW OF ANCHORS WITH SUTURE

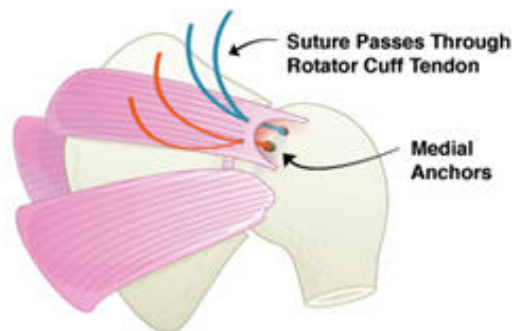


FIG. 4: COMPLETED DOUBLE-ROW ROTATOR CUFF REPAIR

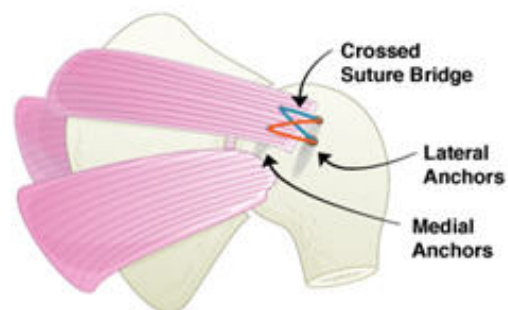


Diagram of Typical Rotator Cuff Repair Technique

As can be seen above, in a typical rotator cuff repair, two anchors are placed directly into the humerus insertion site. Sebastianelli Decl. ¶ 21 (Ex. 1002). The sutures from these two anchors are then drawn through the torn rotator cuff. *Id.* As the surgeon applies tension on the medial sutures, the tendon advances into its proper anatomical position. *Id.* After placing the initial sutures, the surgeon places additional suture anchors (here a third and fourth) lateral to the first two anchors in order to finalize the repair. *Id.* The sutures connected to each of the anchors are connected to each other by a knot or a suture clip either before or after they are tensioned. *See* Feagin '000, col. 2, ll. 57-60 (Ex. 1004); Thal '306, col. 8, ll. 1-5 (Ex. 1005); Sebastianelli Decl. ¶ 21 (Ex. 1002). The connecting step allows the suture anchors to permanently hold the sutures in place, allowing the tendon to remain in its proper position. Sebastianelli Decl. ¶ 21 (Ex. 1002).

As discussed in detail below, it was well known in the art that it was beneficial to have suture anchors and fixation systems that could repair a tissue injury while allowing the surgeon flexibility to control the amount of tension in the repair.

VII. SUMMARY OF THE '073 PATENT AND RELEVANT FILE HISTORY

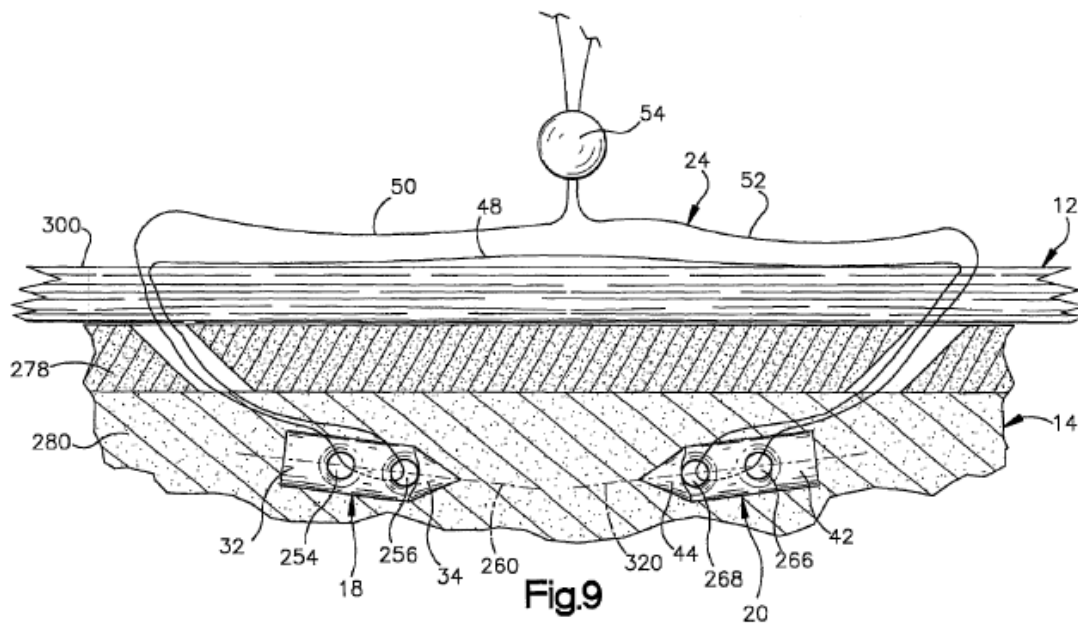
The application that issued as the '073 patent (Ex. 1001) was filed on Apr. 14, 2003. It was a divisional of U.S. patent application Ser. No. 09/789,621, filed

Feb. 21, 2001, now U.S. Pat. No. 6,635,073, which was itself a continuation-in-part of U.S. patent application Ser. No. 09/556,458, filed on May 3, 2000, now U.S. Pat. No. 6,592,609. *See* '073 patent, cover page (Ex. 1001).

A. The '073 Patent

The '073 patent describes methods for attaching body tissues together with a “predetermined tension” by using multiple interconnected suture anchors.

The '073 patent describes an example of the claimed method in Figure 9:



'073 patent, Fig. 9 (Ex. 1001). As depicted in the figure, two anchors (18) and (20) are inserted into a tissue (14) and each has suture (50, 52) that extends out of the tissue. '073 patent, Fig. 9 (Ex. 1001). The suture from the anchors is then interconnected by a separate suture retention device (54). *See* '073 patent, col. 6, ll. 15-21 (Ex. 1001). The '073 patent describes the types of tissue repairs that can

be done using the method: soft to hard (*e.g.*, a tendon to bone); soft to soft (*e.g.*, muscle repair); or hard to hard (*e.g.*, bone to bone). '073 patent, col. 1, ll. 38-44 (Ex. 1001).

With respect to the tension placed on the suture during the repair, the '073 patent states:

A desired tension may be established in the suture by moving the anchors into the body tissue. Alternatively, a desired tension may be established in the suture by applying force to portions of the suture and then interconnecting the portions of the suture. A retainer or a knot may be utilized to interconnect portions of the suture.

'073 patent, col. 2, ll. 1-6 (Ex. 1001). The '073 patent also states, without explanation, that regardless of how the tension is achieved, “it may be desired to establish a predetermined tension in the suture.” '073 patent, col. 28, ll. 41-42 (Ex. 1001). In the example of Figure 9, the sutures are pulled to establish the tension and the suture retainer or “crimp” (54) is used to interconnect the suture ends.

'073 patent, col. 6, ll. 15-16 (Ex. 1001). The '073 patent also states that a knot may be used to interconnect the sutures. '073 patent, col. 6, ll. 17-18 (Ex. 1001).

Fundamentally, and as discussed in greater detail below, the alleged invention of the '073 patent is nothing more than a standard method of repairing tissue using suture anchors.

B. The Challenged Claim of the '073 Patent

The challenged claim of the '073 patent is directed to a method of securing two body tissues together using two suture anchors whose sutures are interconnected and tensioned to a predetermined tension. The challenged claim is reproduced below:

35. A method of securing first body tissue with second body tissue, said method comprising the steps of moving a first anchor along a first path into the second body tissue with a first suture portion extending from the first anchor, moving a second anchor along the second path into the second body tissue with a second suture portion extending from the second anchor, tensioning the first and second suture portions, determining when a predetermined tension is present in the first and second suture portions during performance of said step of tensioning the first and second suture portions, interconnecting the first and second suture portions after determining that the predetermined tension is present in the first and second suture portions, and transmitting force through the suture to the first body tissue.

'073 patent, claim 35 (Ex. 1001).

Claim 35 does no more than claim the use of two standard suture anchors in a predictable way such that their sutures are permanently connected when a desired tension is reached in the repair. There is no question this technique was practiced

years before the priority date of the '073 patent (*i.e.*, May 3, 1999). *See* Sebastianelli Decl. ¶ 24 (Ex. 1002).

C. Summary of the Prosecution History of the '073 Patent

The application that issued as the '073 patent was filed on Apr. 14, 2003. Issued claim 35 appears in the original application. On Jun. 8, 2005, the Examiner issued a restriction requirement. *See* '073 patent file history, Jun. 8, 2005 Office Action (Ex. 1006). The Applicant argued that this restriction was improper and the Examiner withdrew the restriction and rejected all of the claims on the grounds of obviousness type double patenting. *See* '073 patent file history, Sep. 23, 2005 Office Action (Ex. 1007). The Applicant filed a terminal disclaimer to remove this ground of rejection. *See* '073 Patent, cover page (Ex. 1001). The Examiner then issued a notice of allowability. *See* '073 patent file history, Mar. 14, 2005 Notice of Allowability (Ex. 1008). Other than as stated above, Claim 35 was not specifically addressed at any point during prosecution.

VIII. THE PRIOR ART THAT RENDERS THE CHALLENGED CLAIM UNPATENTABLE

The challenged claim recites known or obvious variations of known methods for tissue fixation using multiple suture anchors. *See* Sebastianelli Decl. ¶ 33 (Ex. 1002). The alleged invention is at most the expected result of a combination of

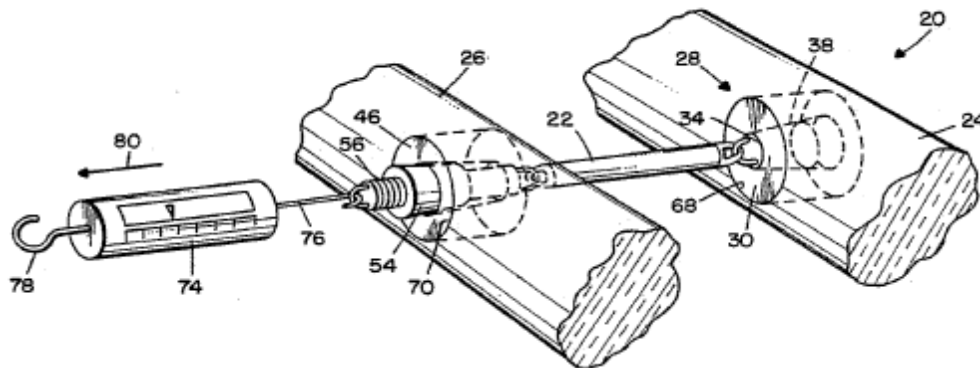
features known by those of skill in the art before the priority date of the '073 patent.

The grounds presented below make clear that the claimed method of securing tissues using multiple suture anchors that are tensioned and connected together was known, or that known methods could have been modified in known ways that would have achieved the expected result of fixation of tissue in the same manner as the claim. *See* Sebastianelli Decl. ¶ 34 (Ex. 1002). Based on the prior art discussed below, claim 35 should be cancelled.

A. The References

1. Bolesky '910

U.S. Patent No. 4,955,910 to Bolesky discloses systems for fixating elongated prosthetic ligaments, pretensioning the ligaments, and installing the ligaments at a “predetermined magnitude of tension.” Bolesky '910, col. 2, ll. 47-50 (Ex. 1003). The disclosed system uses anchors to hold a tendon prosthesis in place between two bones:

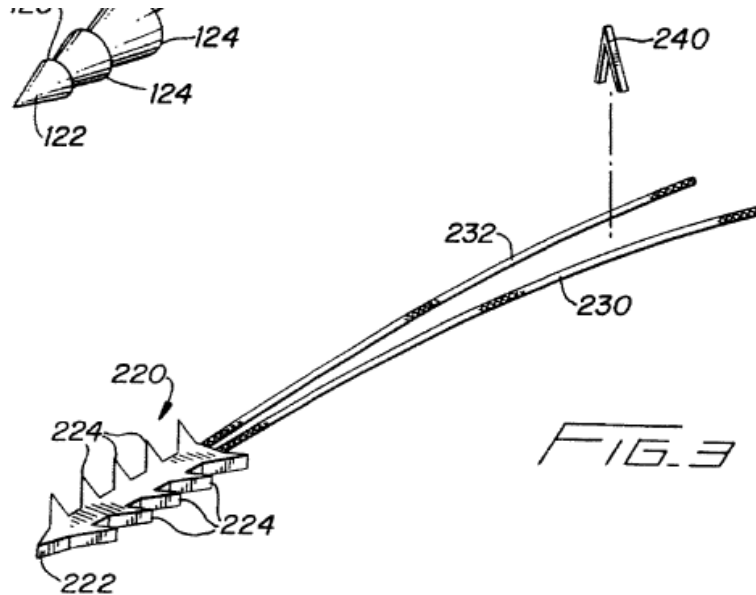


Bolesky '910, Fig. 1 (Ex. 1003). The figure above depicts a synthetic tendon (22) between two bones (26 & 24). Bolesky '910, col. 3, ll. 26-30 (Ex. 1003). That tendon is held in place with two bone anchors (56 & 54). Bolesky '910, col. 4, ll. 6-10 (Ex. 1003). During the surgery, the surgeon attaches an extensiometer (74) to the end of the tendon and pulls it to apply tension to the tendon. Bolesky '910, col. 4, ll. 57-62 (Ex. 1003). Bolesky '910 states that once “a predetermined magnitude of tension has been applied to the [tendon] 22 which is generally in keeping with normal body conditions” the anchor nearest the extensiometer is then deployed to permanently fix the tendon to the bones. Bolesky '910, col. 4, ll. 62-66 (Ex. 1003) (emphasis added). The customizable tension allows this design to be “adjustable to accommodate a variety of required sizes.” Bolesky '910, Abstract; col. 2, ll. 20-24 (Ex. 1003). Bolesky '910 thus teaches that surgeons were aware of how to achieve the proper anatomical functionality of repaired tissue by inserting an anchor and applying a varying amount of tension to the anchored substance until a predetermined amount of tension is achieved. The adjustable methods of Bolesky '910 allow for greater flexibility in the amount of tension placed in surgical repair.

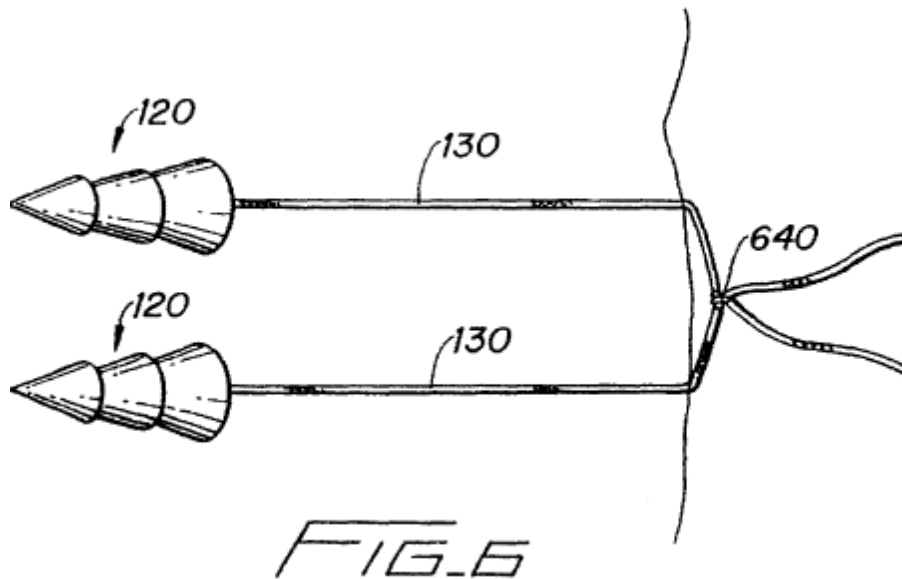
2. Feagin '000

U.S. Patent No. 5,500,000 to Feagin discloses methods of repairing soft tissue comprising “a barbed suture anchoring member attached to at least one suture member [and] a suture retaining member [that] engages the suture member

such that the length and tension can be adjusted before the suture is permanently engaged in the retaining member.” Feagin ’000, Abstract (Ex. 1004). Figure 3 shows one example of a suture anchor and a suture retaining member:



Feagin ’000, Fig. 3 (Ex. 1004). Feagin ’000 teaches that there are two sutures that extend from the anchor portion depicted in Figure 3, and that the “suture retaining member 240 comprises a clip adapted to hold both suture members 232 following tensioning.” Feagin ’000, col. 5, ll. 11-12 (Ex. 1004). Further, Feagin discloses that more than one anchor can be used to accomplish a tissue repair:



Feagin '000, Fig. 6 (Ex. 1004). In Figure 6, two suture anchors are inserted into the tissue in order to accomplish the repair. And “when inserted across a soft tissue defect such as a tear, the suture member of one anchoring member serves as the suture retaining member of the other anchoring member, such as by forming knot 640 from the two suture members.” Feagin '000, col. 5, ll. 43-45 (Ex. 1004).

Feagin '000 describes that “the length and tension of the suture may be selectively adjusted before the suture is permanently engaged in the retaining member,” Feagin '000, col. 2, ll. 57-60 (Ex. 1004), that a “[s]uture retaining member 40 is used to engage suture member 30 such that the length and tension of the suture member may be selected by the user during closure of the tissue,” Feagin '000, col. 4, ll. 15-17 (Ex. 1004), and that “the desired length and tension of the suture member may be achieved for optimal tear closure.” Feagin '000, col. 4, ll. 28-29 (Ex. 1004) (emphases added). In summary, Feagin teaches that it was

known in the art to use multiple suture anchors with attached sutures to repair tissue injuries; that it was known to tension the sutures to a selected tension as desired to complete the repair; and that it was known to interconnect the sutures to complete the fixation.

3. Thal '306

U.S. Patent No. 5,569,306 to Thal discloses methods of using multiple suture anchors to attach tissues together by applying tension to the sutures extending from those anchors and interconnecting the sutures after a desired tension is reached. Figure 10 is a representative example that demonstrates the teachings in Thal '306:

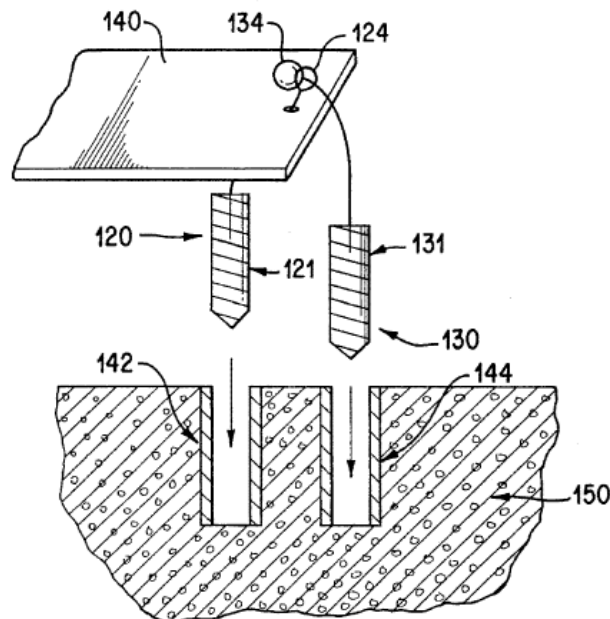


FIG. 10

Thal '306, Fig. 10 (Ex. 1005). The figure above depicts a standard tissue repair wherein the soft tissue (140) is secured to the bone (150) using two suture anchors placed into the bone at two locations. Thal '306, Fig. 10 (Ex. 1005). Sutures are attached to the ends of the two anchors, and, as depicted in the example of Fig. 10, the two sutures are joined together by a “stop means” or ball (134) and a “catch device” or loop (124). Thal '306, Fig. 10 (Ex. 1005). The suture anchors are then inserted into the bone, and the ball and loop connection “drag[s] the tissue into a secure fit with the bone mass.” Thal '306, col. 7, ll. 54-67 (Ex. 1005). Thal '306 makes clear that once the anchors have been inserted, “they can be ratcheted down to a desired depth to adjust the tightness of the soft tissue repair to bone mass.” Thal '306, col. 8, ll. 1-5 (Ex. 1005) (emphasis added). Thal '306, therefore, teaches that it was known in the art to perform a tissue repair using sutures wherein the surgeon adjusts the tension, or tightness, of the repair to a predetermined amount, and that it was known in the art to interconnect multiple sutures used in a repair once the repair is complete.

4. Schaller '107

U.S. Patent No. 5,817,107 to Schaller discloses methods and systems for “fixing a knot in a suture at a remote surgical location,” where a “spring-loaded mechanism enables the applied force to be predetermined for achieving a reliable knot strength.” Schaller '107, Abstract (Ex. 1009). For example, Schaller '107

discloses knot pushers that can measure the force applied to tighten a knot, such as by markings on the knot pusher tube that correspond to the actual force applied. Schaller '107, col. 2, ll. 18-43; Figs. 1-3; col. 3, ll. 34-58 (Ex. 1009). Schaller '107 therefore teaches that it was known in the art to adjust the force applied to tighten a suture knot to yield a predetermined tension in the knot. The adjustable force of Schaller '107 allows for greater flexibility in the amount of tension placed in surgical repair.

IX. IDENTIFICATION OF HOW THE CHALLENGED CLAIM IS UNPATENTABLE

Pursuant to Rule 42.104(b)(4)-(5), specific grounds identified below and discussed in the Sebastianelli Declaration show in detail the prior art disclosures that render the challenged claim unpatentable.

A. Independent Claim 35

Challenged claim 35 covers:

- (a) A method of securing first body tissue with second body tissue, said method comprising the steps of
 - (b) moving a first anchor along a first path into the second body tissue with a first suture portion extending from the first anchor,
 - (c) moving a second anchor along the second path into the second body tissue with a second suture portion extending from the second anchor,

- (d) tensioning the first and second suture portions,
- (e) determining when a predetermined tension is present in the first and second suture portions during performance of said step of tensioning the first and second suture portions,
- (f) interconnecting the first and second suture portions after determining that the predetermined tension is present in the first and second suture portions, and
- (g) transmitting force through the suture to the first body tissue.³

Each of these limitations of claim 35 is shown in the prior art references, as discussed further below.

'073 patent, claim 35 (Ex. 1001); *see* Sebastianelli Decl. ¶ 45 (Ex. 1002).

1. Claim 35 Is Unpatentable Over Feagin '000 in view of Bolesky '910 or Schaller '107

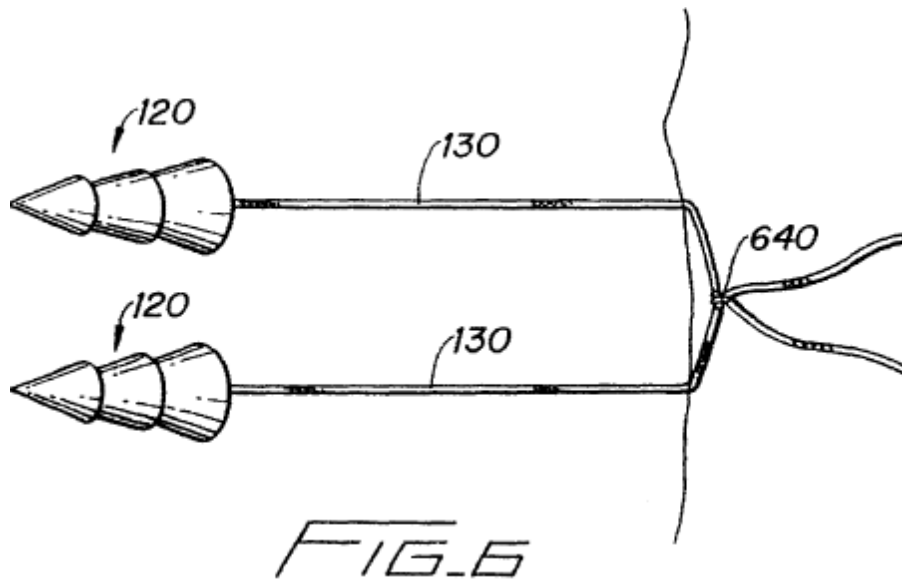
As shown in the summary chart below, and as described in the Sebastianelli Declaration, the method of claim 35 is rendered obvious by the combination of Feagin '000 in view of Bolesky '910 or Schaller '107.

Feagin '000 discloses (a), “[a] method of securing first body tissue with second body tissue, said method comprising the steps of” as recited in the preamble. The embodiments of Feagin '000 discuss the process of repairing a tear

³ The identifiers (a), (b), etc. have been added to the limitations to facilitate discussion of the claims.

in the meniscus of the knee. Feagin '000, col. 2, ll. 49-51 (Ex. 1004); Sebastianelli Decl. ¶ 47 (Ex. 1002). As disclosed in Feagin '000, the tear is repaired by drawing together the two sides of the tear (*i.e.*, first and second body tissue) until they are joined. Feagin '000, col. 6, ll. 25-27 (Ex. 1004); Sebastianelli Decl. ¶ 47 (Ex. 1002). A person of ordinary skill in the art recognizes that a tear in tissue will create separate tissue portions that will need to be rejoined in order to complete the repair. Sebastianelli Decl. ¶ 47 (Ex. 1002). Therefore, the disclosure in Feagin '000 demonstrates the joining of a first and second tissue.

Feagin '000 also discloses (b), “moving a first anchor along a first path into the second body tissue with a first suture portion extending from the first anchor.” As discussed in Feagin '000, the repair method can be used with “a pair of barbed anchoring members having suture members . . . [that can be interconnected] by forming a knot from the two suture members as shown in Fig. 6.” Feagin '000, col. 5, ll. 39-43 (Ex. 1004); Sebastianelli Decl. ¶ 48 (Ex. 1002).



Feagin '000, Fig. 6 (Ex. 1004); Sebastianelli Decl. ¶ 48 (Ex. 1002). As seen in Fig. 6, Feagin '000 also teaches (c), “moving a second anchor along the second path into the second body tissue with a second suture portion extending from the second anchor.” Fig. 6 discloses two anchors, each of which has suture extending from it and is inserted into the same body tissue, but along two different paths. Feagin '000, Fig. 6 (Ex. 1004); Sebastianelli Decl. ¶ 48 (Ex. 1002).

Feagin '000 also teaches (d), “tensioning the first and second suture portions” as required by the claim. Feagin '000 discloses a method of soft tissue repair that uses suture anchors attached to suture and retaining members (*e.g.*, suture clips) that allows the surgeon to adjust the length and tension of the suture “before the suture is permanently engaged in the retaining member.” Feagin '000, col. 2, ll. 59-60 (Ex. 1004); Sebastianelli Decl. ¶ 49 (Ex. 1002). Feagin '000

further discusses the closing of a meniscal tear by “tension[ing]” the suture.

Feagin ’000, col. 6, ll. 25-28 (Ex. 1004); Sebastianelli Decl. ¶ 49 (Ex. 1002).

The step of (e), “determining when a predetermined tension is present in the first and second suture portions during performance of said step of tensioning the first and second suture portions,” is also disclosed in Feagin ’000. Feagin ’000 describes that “the length and tension of the suture may be selectively adjusted before the suture is permanently engaged in the retaining member,” Feagin ’000, col. 2, ll. 57-60 (Ex. 1004), that a “[s]uture retaining member 40 is used to engage suture member 30 such that the length and tension of the suture member may be selected by the user during closure of the tissue,” Feagin ’000, col. 4, ll. 15-17 (Ex. 1004), and that “the desired length and tension of the suture member may be achieved for optimal tear closure.” Feagin ’000, col. 4, ll. 28-29 (Ex. 1004) (emphases added); Sebastianelli Decl. ¶ 50 (Ex. 1002).

To the extent that the Patent Owner argues that step (e) is not disclosed in Feagin, it would have been obvious to a person of ordinary skill in the art to consider Feagin ’000 in view of Bolesky ’910 or Schaller ’107. The person of ordinary skill would be motivated to take the suture anchor techniques of Feagin ’000 and use the adjustable tensioning methods disclosed in Bolesky ’910 or Schaller ’107 to allow for greater flexibility in the amount of tension placed in the surgical repair. Sebastianelli Decl. ¶ 51 (Ex. 1002).

Bolesky '910 teaches a method for installing an artificial tendon between two bones by affixing that tendon to implanted suture anchors and tensioning the tendon such that “a predetermined magnitude of tension has been applied to the [tendon] 22 which is generally in keeping with normal body conditions” prior to the final fixation of the tendon. Bolesky '910, col. 4, ll. 62-66 (Ex. 1003) Sebastianelli Decl. ¶ 52 (Ex. 1002) (emphasis added). Bolesky '910 thus discloses that surgical repairs need to be adjusted in line with normal body conditions and that the surgeon predetermines the magnitude of the tension desired and then applies that tension. Sebastianelli Decl. ¶ 52 (Ex. 1002).

Schaller '107 teaches a method for adjusting the force applied to tighten a suture knot to yield a predetermined tension in the knot: “[a] spring-loaded mechanism enables the applied force to be predetermined for achieving a reliable [suture] knot strength.” Schaller '107, Abstract (Ex. 1009) (emphasis added). For example, Schaller '107 discloses knot pushers that can measure the force applied to tighten a knot, such as by markings on the knot pusher tube that correspond to the actual force applied. Schaller '107, col. 2, ll. 18-43; Figs. 1-3; col. 3, ll. 34-58 (Ex. 1009). Schaller '107 thus discloses that suture knot tension can be adjusted and that the surgeon predetermines the magnitude of the tension desired and then applies that tension. Sebastianelli Decl. ¶ 53 (Ex. 1002).

The person of ordinary skill in the art would have been motivated to take the teachings of Feagin '000 that indicate a need for adjustability and the desire to reach certain levels of tension in a tissue repair and combine them with the teaching of Bolesky '910 or Schaller '107 in a predictable way. *See* Sebastianelli Decl. ¶ 54 (Ex. 1002). This combination creates the known benefit of providing the clinician greater flexibility when determining and providing a desired amount of tension in a surgical repair. The use of adjustable tensioning to effect the desired clinical outcome is known and the result of tensioning a suture or anchored substance to a predetermined value is predictable and expected. The expected outcome is a positive clinical result from the surgery, as suggested by the prior art discussed above. Therefore, it is an obvious combination with no unexpected results. *See* Sebastianelli Decl. ¶ 54 (Ex. 1002).

Feagin '000 also describes (f), “interconnecting the first and second suture portions after determining that the predetermined tension is present in the first and second suture portions” as required by the claim. The methods discussed in Feagin use “[a] disk-shaped button as the suture retaining member.” Feagin '000, col. 6, ll. 25-28 (Ex. 1004); Sebastianelli Decl. ¶ 55 (Ex. 1002). The button is used by drawing the sutures through the hole to allow them to be tensioned and to hold the tension in the suture when the ends of the suture are released: “[a]s the suture member is pulled, [the] button may be pressed against [the] meniscus to aid in the

tensioning process.” Feagin ’000, col. 6, ll. 30-32 (Ex. 1004); Sebastianelli Decl. ¶ 55 (Ex. 1002). In Feagin ’000, the meniscal repair is not complete until “[t]he length of the suture member contained within the meniscus of the knee is . . . fixedly engaged in the suture retaining member as by knotting [or] clipping.” Feagin ’000, col. 6, ll. 34-36 (Ex. 1004); Sebastianelli Decl. ¶ 55 (Ex. 1002).

Finally, Feagin ’000 also teaches (g), “transmitting force through the suture to the first body tissue.” As discussed above, the embodiments of Feagin ’000 show a process of repairing meniscal tears in the knee by drawing together the two sides of the tear with tension (*i.e.*, first and second body tissue) until they are joined, and then completing the repair with a knot. Feagin ’000, col. 6, ll. 25-27; col. 4, ll. 28-29 (Ex. 1004); Sebastianelli Decl. ¶ 56 (Ex. 1002).

The person of ordinary skill in the art could apply the tensioning technique taught by Bolesky ’910 or Schaller ’107 to the surgical repair methods taught in Feagin ’000 and would predictably arrive at the alleged invention in claim 35 of the ’073 patent. Sebastianelli Decl. ¶ 57 (Ex. 1002). The combination of these references is just the predictable application of known methods in the art to achieve the known outcome of a surgical repair that applies a desired amount of tension to the injury. Sebastianelli Decl. ¶ 57 (Ex. 1002). Therefore, the combination of Feagin ’000 in view of Bolesky ’910 or Schaller ’107 discloses each of the limitations of the challenged claim and renders it obvious. Sebastianelli Decl. ¶ 57

(Ex. 1002). The chart below identifies where the above prior art references disclose the limitations of claim 35 of the '073 patent.

Claim 35: (a) A method of securing first body tissue with second body tissue, said method comprising the steps of	<i>See, e.g.,</i> Feagin '000, Abstract; col. 2, ll. 29-32; col. 1, ll. 11-20, 28-34; col. 2, ll. 48-51; col. 3, ll. 1-11; col. 3, ll. 30-32; col. 3, ll. 36-45; col. 6, ll. 25-27; Figs. 7A-7C (Ex. 1004)
(b) moving a first anchor along a first path into the second body tissue with a first suture portion extending from the first anchor,	<i>See, e.g.,</i> Feagin '000, Abstract; col. 2, ll. 29-32, 55-60; col. 5, ll. 3-10; col. 5, ll. 39-43; col. 3, l. 65-col. 4, l. 13; col. 6, ll. 15-24; Figs. 1-6, 7A-7C (Ex. 1004)
(c) moving a second anchor along the second path into the second body tissue with a second suture portion extending from the second anchor,	<i>See, e.g.,</i> Feagin '000, Abstract; col. 2, ll. 29-32, 55-60; col. 5, ll. 3-10; col. 5, ll. 39-43; col. 3, l. 65-col. 4, l. 13; col. 6, ll. 15-24; Figs. 1-6, 7A-7C (Ex. 1004)
(d) tensioning the first and second suture portions,	<i>See, e.g.,</i> Feagin '000, Abstract; col. 2, ll. 35-43, 55-60; col. 3, ll. 6-11; col. 4, ll. 14-17, 25-29, 56-61; col. 6, ll. 25-37; Figs. 7A-7C (Ex. 1004)
(e) determining when a predetermined tension is present in the first and second suture portions during performance of said step of tensioning the first and second suture portions,	<p><i>See, e.g.,</i> Feagin '000, Abstract; col. 2, ll. 35-43, 57-60; col. 4, ll. 15-17; col. 4, ll. 28-29 (Ex. 1004)</p> <p><i>See, e.g.,</i> Bolesky '910, Abstract; col. 2, ll. 3-13, 19-26, 45-50; col. 4, ll. 59-66; col. 5, ll. 16-20, 54-59; col. 6, ll. 3-8; col. 7, ll. 9-20, 38-46; col. 8, ll. 48-55 (Ex. 1003)</p> <p><i>See, e.g.,</i> Schaller '107, Abstract; col. 2, ll. 18-43; Figs. 1-3; col. 3, ll. 34-58 (Ex. 1009).</p>

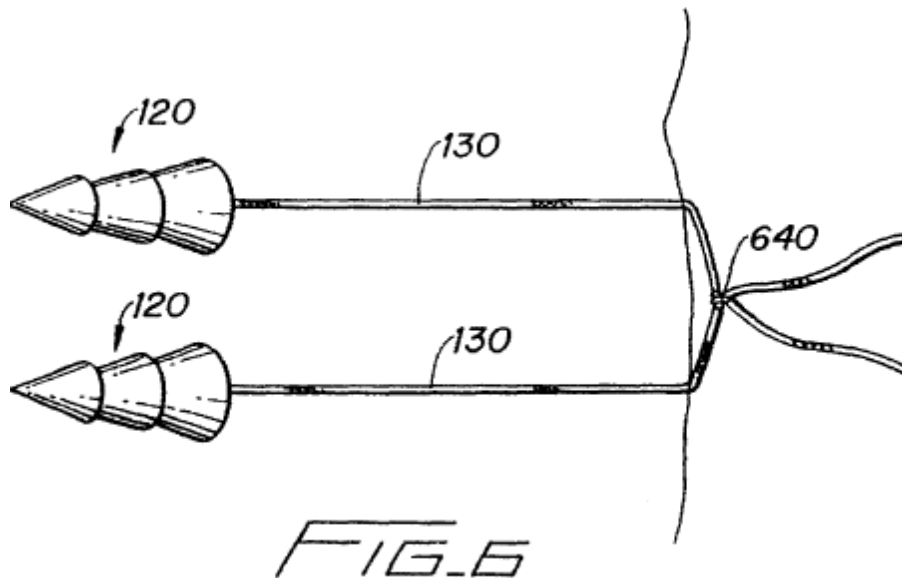
(f) interconnecting the first and second suture portions after determining that the predetermined tension is present in the first and second suture portions, and	<i>See, e.g.</i> , Feagin '000, Abstract; col. 2, ll. 33-35; col. 4, ll. 14-36; col. 4, ll. 50-61; col. 4, ll. 11-24; col. 5, ll. 11-23, 34-37; col. 6, ll. 25-28; col. 6, ll. 30-32; col. 6, ll. 34-36, 39-49; Figs. 1-6 (Ex. 1004)
(g) transmitting force through the suture to the first body tissue.	<i>See, e.g.</i> , Feagin '000, Abstract; col. 2, ll. 61-64; col. 3, ll. 1-11; col. 3, ll. 30-32; col. 3, ll. 36-45; col. 6, ll. 25-27; Figs. 7A-7C (Ex. 1004)

2. Claim 35 Is Unpatentable Over Feagin '000

As shown in the summary chart below, and in the Sebastianelli Declaration, the method of claim 35 is anticipated by Feagin '000.

Feagin '000 discloses (a), “[a] method of securing first body tissue with second body tissue, said method comprising the steps of” as recited in the preamble. The embodiments of Feagin '000 discuss the process of repairing a tear in the meniscus of the knee. Feagin '000, col. 2, ll. 49-51 (Ex. 1004); Sebastianelli Decl. ¶ 59 (Ex. 1002). As disclosed in Feagin '000, the tear is repaired by drawing together the two sides of the tear (*i.e.*, first and second body tissue) until they are joined. Feagin '000, col. 6, ll. 25-27 (Ex. 1004); Sebastianelli Decl. ¶ 59 (Ex. 1002). A person of ordinary skill in the art recognizes that a tear in tissue will create separate tissue portions that will need to be rejoined in order to complete the repair. Sebastianelli Decl. ¶ 59 (Ex. 1002). Therefore, the disclosure in Feagin '000 demonstrates the joining of a first and second tissue.

Feagin '000 also discloses (b), “moving a first anchor along a first path into the second body tissue with a first suture portion extending from the first anchor.” As discussed in Feagin '000, the repair method can be used with “a pair of barbed anchoring members having suture members . . . [that can be interconnected] by forming a knot from the two suture members as shown in Fig. 6.” Feagin '000, col. 5, ll. 39-43 (Ex. 1004); Sebastianelli Decl. ¶ 60 (Ex. 1002).



Feagin '000, Fig. 6 (Ex. 1004); Sebastianelli Decl. ¶ 60 (Ex. 1002). As seen in Figure 6, Feagin '000 also teaches (c), “moving a second anchor along the second path into the second body tissue with a second suture portion extending from the second anchor.” Figure 6 discloses two anchors, each of which has suture extending from it and is inserted into the same body tissue, but along two different paths. Feagin '000, Fig. 6 (Ex. 1004); Sebastianelli Decl. ¶ 60 (Ex. 1002).

Feagin '000 also teaches (d), “tensioning the first and second suture portions” as required by the claim. Feagin '000 discloses a method of soft tissue repair that uses suture anchors attached to suture and retaining members (*e.g.*, suture clips) that allows the surgeon to adjust the length and tension of the suture “before the suture is permanently engaged in the retaining member.” Feagin '000, col. 2, ll. 59-60 (Ex. 1004); Sebastianelli Decl. ¶ 61 (Ex. 1002). Feagin '000 further discusses the closing of a meniscal tear by “tension[ing]” the suture. Feagin '000, col. 6, ll. 25-28 (Ex. 1004); Sebastianelli Decl. ¶ 61 (Ex. 1002).

The step of (e), “determining when a predetermined tension is present in the first and second suture portions during performance of said step of tensioning the first and second suture portions,” is also disclosed in Feagin '000. Feagin '000 describes that “the length and tension of the suture may be selectively adjusted before the suture is permanently engaged in the retaining member,” Feagin '000, col. 2, ll. 57-60 (Ex. 1004), that a “[s]uture retaining member 40 is used to engage suture member 30 such that the length and tension of the suture member may be selected by the user during closure of the tissue,” Feagin '000, col. 4, ll. 15-17 (Ex. 1004), and that “the desired length and tension of the suture member may be achieved for optimal tear closure.” Feagin '000, col. 4, ll. 28-29 (Ex. 1004) (emphases added); Sebastianelli Decl. ¶ 62 (Ex. 1002).

Feagin '000 also describes (f), “interconnecting the first and second suture portions after determining that the predetermined tension is present in the first and second suture portions, and” as required by the claim. The methods discussed in Feagin use “[a] disk-shaped button as the suture retaining member.” Feagin '000, col. 6, ll. 25-28 (Ex. 1004); Sebastianelli Decl. ¶ 63 (Ex. 1002). The button is used by drawing the sutures through the hole to allow them to be tensioned and to hold the tension in the suture when the ends of the suture are released: “[a]s the suture member is pulled, [the] button may be pressed against [the] meniscus to aid in the tensioning process.” Feagin '000, col. 6, ll. 30-32 (Ex. 1004); Sebastianelli Decl. ¶ 63 (Ex. 1002). In Feagin '000, the meniscal repair is not complete until “[t]he length of the suture member contained within the meniscus of the knee is . . . fixedly engaged in the suture retaining member as by knotting [or] clipping.” Feagin '000, col. 6, ll. 34-36 (Ex. 1004); Sebastianelli Decl. ¶ 63 (Ex. 1002).

Finally, Feagin '000 also teaches (g), “transmitting force through the suture to the first body tissue.” As discussed above, the embodiments of Feagin '000 show a process of repairing meniscal tears in the knee by drawing together the two sides of the tear with tension (*i.e.*, first and second body tissue) until they are joined, and then completing the repair with a knot. Feagin '000, col. 6, ll. 25-27; col. 4, ll. 28-29 (Ex. 1004); Sebastianelli Decl. ¶ 64 (Ex. 1002).

Therefore, Feagin '000 discloses each of the limitations of the challenged claim and renders it anticipated. The chart below identifies where the above prior art reference discloses the limitations of claim 35 of the '073 patent.

Claim 35: (a) A method of securing first body tissue with second body tissue, said method comprising the steps of	<i>See, e.g.,</i> Feagin '000, Abstract; col. 2, ll. 29-32; col. 1, ll. 11-20, 28-34; col. 2, ll. 48-51; col. 3, ll. 1-11; col. 3, ll. 30-32; col. 3, ll. 36-45; col. 6, ll. 25-27; Figs. 7A-7C (Ex. 1004)
(b) moving a first anchor along a first path into the second body tissue with a first suture portion extending from the first anchor,	<i>See, e.g.,</i> Feagin '000, Abstract; col. 2, ll. 29-32, 55-60; col. 5, ll. 3-10; col. 5, ll. 39-43; col. 3, l. 65-col. 4, l. 13; col. 6, ll. 15-24; Figs. 1-6, 7A-7C (Ex. 1004)
(c) moving a second anchor along the second path into the second body tissue with a second suture portion extending from the second anchor,	<i>See, e.g.,</i> Feagin '000, Abstract; col. 2, ll. 29-32, 55-60; col. 5, ll. 3-10; col. 5, ll. 39-43; col. 3, l. 65-col. 4, l. 13; col. 6, ll. 15-24; Figs. 1-6, 7A-7C (Ex. 1004)
(d) tensioning the first and second suture portions,	<i>See, e.g.,</i> Feagin '000, Abstract; col. 2, ll. 35-43, 55-60; col. 3, ll. 6-11; col. 4, ll. 14-17, 25-29, 56-61; col. 6, ll. 25-37; Figs. 7A-7C (Ex. 1004)
(e) determining when a predetermined tension is present in the first and second suture portions during performance of said step of tensioning the first and second suture portions,	<i>See, e.g.,</i> Feagin '000, Abstract; col. 2, ll. 35-43, 57-60; col. 4, ll. 15-17; col. 4, ll. 28-29 (Ex. 1004)
(f) interconnecting the first and second suture portions after determining that the predetermined tension is present in the first and second suture portions, and	<i>See, e.g.,</i> Feagin '000, Abstract; col. 2, ll. 33-35; col. 4, ll. 14-36; col. 4, ll. 50-61; col. 4, ll. 11-24; col. 5, ll. 11—23, 34-37; col. 6, ll. 25-28; col. 6, ll. 30-32; col. 6, ll. 34-36, 39-49; Figs. 1-6 (Ex. 1004)

(g) transmitting force through the suture to the first body tissue.	<i>See, e.g.,</i> Feagin '000, Abstract; col. 2, ll. 61-64; col. 3, ll. 1-11; col. 3, ll. 30-32; col. 3, ll. 36-45; col. 6, ll. 25-27; Figs. 7A-7C (Ex. 1004)
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3. Claim 35 is Unpatentable Over Thal '306 in View of Bolesky '910 or Schaller '107

As shown in the summary chart below, and in the Sebastianelli Declaration, the method of claim 35 is rendered obvious by Thal '306 in view of Bolesky '910 or Schaller '107.

Thal '306 discloses limitation (a), “[a] method of securing first body tissue with second body tissue, said method comprising the steps of.” Figure 15 depicts this element of the claim:

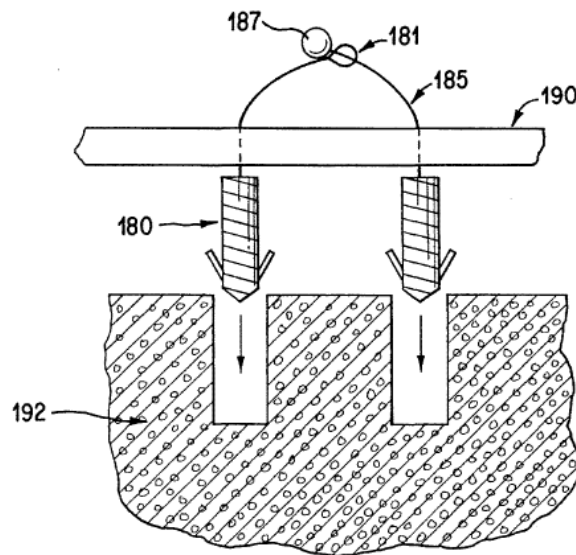


FIG. 15

Thal '306, Fig. 15 (Ex. 1005); Sebastianelli Decl. ¶ 67 (Ex. 1002). Thal '306 discloses that two tissues (192) and (190) are joined together by two anchors (180) and (185). Thal '306, col. 8, ll. 54-56 (Ex. 1005); Sebastianelli Decl. ¶ 67 (Ex. 1002). Further, Thal '306 teaches (b), “moving a first anchor along a first path into the second body tissue with a first suture portion extending from the first anchor,” and (c), “moving a second anchor along the second path into the second body tissue with a second suture portion extending from the second anchor.” Thal '306 depicts two separate paths into the tissue (192) (shown with downward arrows in Figure 15 above and described in the specification). Thal '306, col. 8, ll. 49-56 (Ex. 1005); Sebastianelli Decl. ¶ 67 (Ex. 1002). Each of the anchors has a suture portion attached to the end of the anchor: the “other end [has] a means for attachment of a suture material.” Thal '306, col. 2, ll. 59-60 (Ex. 1005); Sebastianelli Decl. ¶ 67 (Ex. 1002).

Thal '306 also teaches (d), “tensioning the first and second suture portions.” As described by Thal '306, “[t]he sutures 183 and 188 are pulled taught to securely attach soft tissue 190 to bone mass 192.” Thal '306, col. 8, ll. 42-48 (Ex. 1005); Sebastianelli Decl. ¶ 68 (Ex. 1002).

The step of (e), “determining when a predetermined tension is present in the first and second suture portions during performance of said step of tensioning the first and second suture portions,” is also described in Thal '306. Specifically, Thal

'306 teaches that the “tightness of the soft tissue repair” can be adjusted as needed. Thal '306, col. 8, ll. 1-5 (Ex. 1005); Sebastianelli Decl. ¶ 69 (Ex. 1002). Thal '306 thus recognizes that surgical repairs need to be adjusted to the proper tension as predetermined by the surgeon.

To the extent that the Patent Owner argues that step (e) is not disclosed in Thal '306, it would have been obvious to a person of ordinary skill in the art to consider Thal '306 in view of Bolesky '910 or Schaller '107. Sebastianelli Decl. ¶ 70 (Ex. 1002). The person of ordinary skill would be motivated to take the suture anchor techniques of Thal '306 and use the adjustable tensioning techniques disclosed in Bolesky '910 or Schaller '107 to allow for greater flexibility in the amount of tension placed in the surgical repair. Sebastianelli Decl. ¶ 70 (Ex. 1002).

Bolesky '910 teaches a method for installing an artificial tendon between two bones by affixing that tendon to implanted suture anchors and tensioning the tendon such that “a predetermined magnitude of tension has been applied to the [tendon] 22 which is generally in keeping with normal body conditions” prior to the final fixation of the tendon. Bolesky '910, col. 4, ll. 62-66 (Ex. 1003); Sebastianelli Decl. ¶ 71 (Ex. 1002). Bolesky '910 recognizes that surgical repairs need to be adjusted in line with normal body conditions and that the surgeon

predetermines the magnitude of the tension desired and then applies that tension.

Sebastianelli Decl. ¶ 71 (Ex. 1002).

Schaller '107 teaches a method for adjusting the force applied to tighten a suture knot to yield a predetermined tension in the knot: “[a] spring-loaded mechanism enables the applied force to be predetermined for achieving a reliable [suture] knot strength.” Schaller '107, Abstract (Ex. 1009) (emphasis added). For example, Schaller '107 discloses knot pushers that can measure the force applied to tighten a knot, such as by markings on the knot pusher tube corresponding to the actual force applied. Schaller '107, col. 2, ll. 18-43; Figs. 1-3; col. 3, ll. 34-58 (Ex. 1009). Schaller '107 thus discloses that suture knot tension can be adjusted and that the surgeon predetermines the magnitude of the tension desired and then applies that tension. Sebastianelli Decl. ¶ 72 (Ex. 1002).

The person of ordinary skill in the art would have been motivated to take the teachings of Thal '306 that indicate a need for adjustability and the desire to reach certain levels of tension in a tissue repair and combine them with the teachings of Bolesky '910 or Schaller '107, which expressly state that a predetermined tension can be applied to a surgical repair. This combination creates the known benefit of providing the clinician greater flexibility when determining and providing a desired amount of tension in a surgical repair. The use of adjustable tensioning to effect the desired clinical outcome is known and the result of tensioning a suture or

anchored substance to a predetermined value is predictable and expected. The expected outcome is a positive clinical result from the surgery, as suggested by the prior art discussed above. Therefore, it is an obvious combination with no unexpected results. *See* Sebastianelli Decl. ¶ 73 (Ex. 1002).

Thal '306 also describes step (f), “interconnecting the first and second suture portions after determining that the predetermined tension is present in the first and second suture portions, and.” The ends of the sutures in the devices of Thal '306 are designed to be interconnected together to hold the tissue in place once the repair is complete. Thal '306, col. 7, ll. 31-34 (Ex. 1005); Sebastianelli Decl. ¶ 74 (Ex. 1002). When practicing the method in Figure 15, the loop (181) of a suture attached to the first anchor (180) is inserted through soft tissue (190) from the underside of the tissue. Thal '306, col. 8, ll. 49-56 (Ex. 1005); Sebastianelli Decl. ¶ 74 (Ex. 1002). That anchor is then inserted into the bone (192). Thal '306, col. 8, ll. 49-56 (Ex. 1005); Sebastianelli Decl. ¶ 74 (Ex. 1002). The suture portion of the second anchor is also threaded through the tissue. Thal '306, col. 8, ll. 49-56 (Ex. 1005); Sebastianelli Decl. ¶ 74 (Ex. 1002). The second anchor is also deployed in the bone. Thal '306, col. 8, ll. 49-56 (Ex. 1005); Sebastianelli Decl. ¶ 64 (Ex. 1002). The two suture portions are joined with the ball and loop. Thal '306, col. 8, ll. 49-56 (Ex. 1005); Sebastianelli Decl. ¶ 74 (Ex. 1002).

The Patent Owner may argue that claim 35 requires that the interconnecting step (f) must occur after the tensioning step (e), and that because Thal '306 discloses interconnecting the sutures attached to the anchors before tensioning, Thal '306 is not sufficient to render the claim obvious. Steps of a method claim are not required to be performed in order absent disclosure to the contrary. *See, e.g., Altirus, Inc. v. Symantec Corp.*, 318 F.3d 1362, 1369 (Fed. Cir. 2003). Even if it were correct that the claim requires a specific order, which it does not, the Thal '306 reference still renders the claims obvious. Sebastianelli Decl. ¶ 75 (Ex. 1002). It is well within the skill of one in the art to use the method shown in Fig. 15 and tension the sutures after inserting the anchors but before the loop and ball of the sutures are connected. Sebastianelli Decl. ¶ 75 (Ex. 1002). As discussed above, tensioning sutures before tying them together (*i.e.*, interconnecting them) was a well-known practice in the art. Sebastianelli Decl. ¶ 75 (Ex. 1002). Moreover, there is nothing in the prior art, or in the description of the alleged invention of the '073 patent, that indicates that the order of steps (e) and (f) provides any unexpected benefit. Sebastianelli Decl. ¶ 75 (Ex. 1002). Therefore, even if the claim requires that step (e) tensioning is required before step (f) interconnecting, that is obvious from the teaching of Thal '306. Sebastianelli Decl. ¶ 75 (Ex. 1002).

Finally, Thal '306 teaches (g), “transmitting force through the suture to the first body tissue.” During the procedure, the surgeon uses the sutures connected to the anchors to “drag the tissue into a secure fit with the bone mass.” Thal '306, col. 7, ll. 54-67 (Ex. 1005); Sebastianelli Decl. ¶ 76 (Ex. 1002).

The person of ordinary skill in the art could apply the tensioning technique taught by Bolesky '910 or Schaller '107 to the surgical repair methods taught in Thal '306 and would predictably arrive at the alleged invention in claim 35 of the '073 patent. Sebastianelli Decl. ¶ 77 (Ex. 1002). The combination of these references is just the predictable application of known methods in the art to achieve the known outcome of a surgical repair that applies a desired amount of tension to the injury. Sebastianelli Decl. ¶ 77 (Ex. 1002). Therefore, the combination of Thal '306 in view of Bolesky '910 or Schaller '107 discloses each of the limitations of the challenged claim and renders it obvious. Sebastianelli Decl. ¶ 77 (Ex. 1002). The chart below identifies where the above prior art references disclose the limitations of claim 35 of the '073 patent.

Claim 35: (a) A method of securing first body tissue with second body tissue, said method comprising the steps of	<i>See, e.g.</i> , Thal '306, Abstract, Figs. 4, 5, 7, 8, 10-11, 13, 15; col. 2, ll. 13-16, 29-31; col. 6, ll. 20-29; col. 8, ll. 54-56 (Ex. 1005)
(b) moving a first anchor along a first path into the second body tissue with a first suture portion extending from the first anchor,	<i>See, e.g.</i> , Thal '306, Abstract; Figs. 2, 4-21; col. 2, ll. 59-60; col. 2, l. 64-col. 3, l. 6; col. 7, l. 54-col. 8, l. 14; col. 8, ll. 49-56 (Ex. 1005)

(c) moving a second anchor along the second path into the second body tissue with a second suture portion extending from the second anchor,	<i>See, e.g.</i> , Thal '306, Abstract; Figs. 2, 4-21; col. 2, ll. 59-60; col. 2, l. 64-col. 3, l. 6; col. 7, l. 54-col. 8, l. 14; col. 8, ll. 49-56 (Ex. 1005)
(d) tensioning the first and second suture portions,	<i>See, e.g.</i> , Thal '306, Abstract; col. 3, ll.19-32, 39-51; col. 6. ll. 2-14; col. 7, ll. 7-12, 63-66; col. 8, ll. 1-5, 32-40, 42-48 (Ex. 1005)
(e) determining when a predetermined tension is present in the first and second suture portions during performance of said step of tensioning the first and second suture portions,	<p><i>See, e.g.</i>, Thal '306, Abstract; col. 3, ll.19-32, 39-51; col. 6. ll. 2-14; col. 7, ll. 7-12, 63-66; col. 8, ll. 1-5, 32-40, 42-48 (Ex. 1005)</p> <p><i>See, e.g.</i>, Bolesky '910, Abstract; col. 2, ll. 3-13, 19-26, 45-50; col. 4, ll. 59-66; col. 5, ll. 16-20, 54-59; col. 6, ll. 3-8; col. 7, ll. 9-20, 38-46; col. 8, ll. 48-55 (Ex. 1003)</p> <p><i>See, e.g.</i>, Schaller '107, Abstract; col. 2, ll. 18-43; Figs. 1-3; col. 3, ll. 34-58 (Ex. 1009)</p>
(f) interconnecting the first and second suture portions after determining that the predetermined tension is present in the first and second suture portions, and	<i>See, e.g.</i> , Thal '306, Abstract; Figs. 9, 10, 11, 14, 15; col. 3, ll. 19-32; col. 7, l. 14-col. 8, l. 14; col. 7, ll. 31-34; col. 8, ll.41-56; col. 8, ll. 49-56 (Ex. 1005)
(g) transmitting force through the suture to the first body tissue.	<i>See, e.g.</i> , Thal '306, Abstract; col. 3, ll.19-32, 39-51; col. 6. ll. 2-14; col. 7, ll. 7-12, 63-66; col. 8, ll. 1-5, 32-40, 42-48 (Ex. 1005)

4. Claim 35 is Unpatentable Over Thal '306

As shown in the summary chart below, and in the Sebastianelli Declaration, the method of claim 35 is anticipated or, in the alternative, rendered obvious by Thal '306.

Thal '306 discloses limitation (a), “[a] method of securing first body tissue with second body tissue, said method comprising the steps of.” Figure 15 depicts this element of the claim:

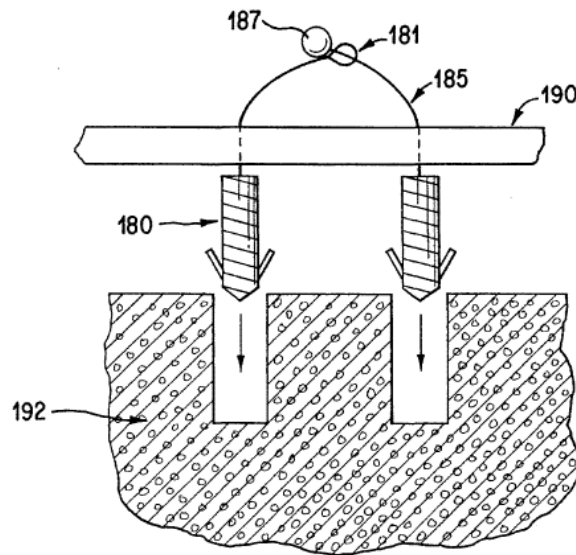


FIG. 15

Thal '306, Fig. 15 (Ex. 1005); Sebastianelli Decl. ¶ 79 (Ex. 1002). Thal '306 discloses that two tissues (192) and (190) are joined together by two anchors (180) and (185). Thal '306, col. 8, ll. 54-56 (Ex. 1005); Sebastianelli Decl. ¶ 79 (Ex. 1002). Further, Thal '306 teaches (b), “moving a first anchor along a first path into

the second body tissue with a first suture portion extending from the first anchor,” and (c), “moving a second anchor along the second path into the second body tissue with a second suture portion extending from the second anchor.” Thal ’306 depicts two separate paths into the tissue (192) (shown with downward arrows in Figure 15 above and described in the specification). Thal ’306, col. 8, ll. 49-56 (Ex. 1005); Sebastianelli Decl. ¶ 79 (Ex. 1002). Each of the anchors has a suture portion attached to the end of the anchor: the “other end [has] a means for attachment of a suture material.” Thal ’306, col. 2, ll. 59-60 (Ex. 1005); Sebastianelli Decl. ¶ 79 (Ex. 1002).

Thal ’306 also teaches (d), “tensioning the first and second suture portions.” As described by Thal ’306, “[t]he sutures 183 and 188 are pulled taught to securely attach soft tissue 190 to bone mass 192.” Thal ’306, col. 8, ll. 42-48 (Ex. 1005) Sebastianelli Decl. ¶ 80 (Ex. 1002).

The step of (e), “determining when a predetermined tension is present in the first and second suture portions during performance of said step of tensioning the first and second suture portions,” is also described in Thal ’306. Specifically, Thal ’306 it teaches that the “tightness of the soft tissue repair” can be adjusted as needed. Thal ’306, col. 8, ll. 1-5 (Ex. 1005); Sebastianelli Decl. ¶ 81 (Ex. 1002). Thal ’306 thus recognizes that surgical repairs need to be adjusted to the proper tension as predetermined by the surgeon.

Thal '306 also describes step (f), “interconnecting the first and second suture portions after determining that the predetermined tension is present in the first and second suture portions.” The ends of the sutures in the devices of Thal '306 are designed to be interconnected together to hold the tissue in place once the repair is complete. Thal '306, col. 7, ll. 31-34 (Ex. 1005); Sebastianelli Decl. ¶ 82 (Ex. 1002). When practicing the method in Figure 15, the loop (181) of a suture attached to the first anchor (180) is inserted through soft tissue (190) from the underside of the tissue. Thal '306, col. 8, ll. 49-56 (Ex. 1005); Sebastianelli Decl. ¶ 82 (Ex. 1002). That anchor is then inserted into the bone (192). Thal '306, col. 8, ll. 49-56 (Ex. 1005); Sebastianelli Decl. ¶ 82 (Ex. 1002). The suture portion of the second anchor is also threaded through the tissue. Thal '306, col. 8, ll. 49-56 (Ex. 1005); Sebastianelli Decl. ¶ 82 (Ex. 1002). The second anchor is also deployed in the bone. Thal '306, col. 8, ll. 49-56 (Ex. 1005); Sebastianelli Decl. ¶ 82 (Ex. 1002). The two suture portions are joined with the ball and loop. Thal '306, col. 8, ll. 49-56 (Ex. 1005); Sebastianelli Decl. ¶ 82 (Ex. 1002).

The Patent Owner may argue that claim 35 requires that the interconnecting step (f) must occur after the tensioning step (e), and that because Thal '306 discloses interconnecting the sutures attached to the anchors before tensioning, Thal '306 is not sufficient to render the claim obvious. Steps of a method claim are not required to be performed in order absent disclosure to the contrary. *See,*

e.g., Altirus, Inc. v. Symantec Corp., 318 F.3d 1362, 1369 (Fed. Cir. 2003). Even if it were correct that the claim requires a specific order, which it does not, the Thal '306 reference still renders the claims obvious. Sebastianelli Decl. ¶ 83 (Ex. 1002). It is well within the skill of one in the art to use the method shown in Figure 15 and tension the sutures after inserting the anchors but before the loop and ball of the sutures are connected. Sebastianelli Decl. ¶ 83 (Ex. 1002). As discussed above, tensioning sutures before tying them together (*i.e.*, interconnecting them) was a well-known practice in the art. Sebastianelli Decl. ¶ 83 (Ex. 1002). Moreover, there is nothing in the prior art, or in the description of the alleged invention of the '073 patent, that indicates that the order of steps (e) and (f) provides any unexpected benefit. Sebastianelli Decl. ¶ 83 (Ex. 1002). Therefore, even if the claim requires that step (e) tensioning is required before step (f) interconnecting, that is obvious from the teaching of Thal '306. Sebastianelli Decl. ¶ 83 (Ex. 1002).

Finally, Thal '306 teaches (g), “transmitting force through the suture to the first body tissue.” During the procedure, the surgeon uses the sutures connected to the anchors to “drag the tissue into a secure fit with the bone mass.” Thal '306, col. 7, ll. 54-67 (Ex. 1005); Sebastianelli Decl. ¶ 84 (Ex. 1002).

Therefore, Thal '306 discloses each of the limitations of the challenged claim and renders it anticipated or, in the alternative, obvious. The chart below

identifies where the above prior art reference discloses the limitations of claim 35 of the '073 patent.

Claim 35: (a) A method of securing first body tissue with second body tissue, said method comprising the steps of	<i>See, e.g.,</i> Thal '306, Abstract, Figs. 4, 5, 7, 8, 10-11, 13, 15; col. 2, ll. 13-16, 29-31; col. 6, ll. 20-29; col. 8, ll. 54-56 (Ex. 1005)
(b) moving a first anchor along a first path into the second body tissue with a first suture portion extending from the first anchor,	<i>See, e.g.,</i> Thal '306, Abstract; Figs. 2, 4-21; col. 2, ll. 59-60; col. 2, l. 64-col. 3, l. 6; col. 7, l. 54-col. 8, l. 14; col. 8, ll. 49-56 (Ex. 1005)
(c) moving a second anchor along the second path into the second body tissue with a second suture portion extending from the second anchor,	<i>See, e.g.,</i> Thal '306, Abstract; Figs. 2, 4-21; col. 2, ll. 59-60; col. 2, l. 64-col. 3, l. 6; col. 7, l. 54-col. 8, l. 14; col. 8, ll. 49-56 (Ex. 1005)
(d) tensioning the first and second suture portions,	<i>See, e.g.,</i> Thal '306, Abstract; col. 3, ll.19-32, 39-51; col. 6. ll. 2-14; col. 7, ll. 7-12, 63-66; col. 8, ll. 1-5, 32-40, 42-48 (Ex. 1005)
(e) determining when a predetermined tension is present in the first and second suture portions during performance of said step of tensioning the first and second suture portions,	<i>See, e.g.,</i> Thal '306, Abstract; col. 3, ll.19-32, 39-51; col. 6. ll. 2-14; col. 7, ll. 7-12, 63-66; col. 8, ll. 1-5, 32-40, 42-48 (Ex. 1005)
(f) interconnecting the first and second suture portions after determining that the predetermined tension is present in the first and second suture portions, and	<i>See, e.g.,</i> Thal '306, Abstract; Figs. 9, 10, 11, 14, 15; col. 3, ll. 19-32; col. 7, l. 14-col. 8, l. 14; col. 7, ll. 31-34; col. 8, ll.41-56; col. 8, ll. 49-56 (Ex. 1005)
(g) transmitting force through the suture to the first body tissue.	<i>See, e.g.,</i> Thal '306, Abstract; col. 3, ll.19-32, 39-51; col. 6. ll. 2-14; col. 7, ll. 7-12, 63-66; col. 8, ll. 1-5, 32-40, 42-48 (Ex. 1005)

X. CONCLUSION

Based on the foregoing, claim 35 of the '073 patent recites subject matter that is unpatentable. The Petitioner requests institution of an *inter partes* review to cancel that claim.

Respectfully submitted,

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LIST OF EXHIBITS FOR
PETITION FOR *INTER PARTES* REVIEW OF
U.S. PATENT NO. 7,087,073

<u>Exhibit</u>	<u>Description</u>
1001	U.S. Patent No. 7,087,073 (“’073 patent”)
1002	Declaration of Dr. Wayne J. Sebastianelli (“Sebastianelli Declaration” or “Sebastianelli Decl.”)
1003	U.S. Patent No. 4,955,910 (“Bolesky ’910”)
1004	U.S. Patent No. 5,500,000 (“Feagin ’000”)
1005	U.S. Patent No. 5,569,306 (“Thal ’306”)
1006	’073 patent file history, Jun. 8, 2005 Office Action
1007	’073 patent file history, Sep. 23, 2005 Office Action
1008	’073 patent file history, Mar. 14, 2005 Notice of Allowability
1009	U.S. Patent No. 5,817,107 (“Schaller ’107”)

CERTIFICATE OF SERVICE

I hereby certify that on September 24, 2013, I caused a true and correct copy of the foregoing materials:

- Petition for *Inter Partes* Review of U.S. Patent No. 7,087,073 Under 35 U.S.C. § 312 and 37 C.F.R. § 42.104
- Exhibits 1001-1009
- List of Exhibits for Petition for *Inter Partes* Review of U.S. Patent No. 7,087,073 (Exhibits 1001-1009)
- Fee Authorization
- Power of Attorney

to be served via Federal Express on the following attorney of record as listed on PAIR:

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